PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: A61B 17/70

(11) International Publication Number:

WO 97/09940

(43) International Publication Date:

20 March 1997 (20.03.97)

(21) International Application Number:

PCT/NZ96/00096

(22) International Filing Date:

11 September 1996 (11.09.96)

(30) Priority Data:

272994

12 September 1995 (12.09.95) NZ

(71)(72) Applicants and Inventors: CATHRO, Richard, Andrew [NZ/NZ]; 97 Abbots Hill Road, Dunedin (NZ). GILLETT, Grant, Randall [NZ/NZ]; 164 Maitland Street, Dunedin

(74) Agents: BENNETT. Michael, R. et al.; A.J. Park & Son, Huddart Parker Building, 6th floor, Post Office Square, P.O. Box 949, Wellington 6015 (NZ).

(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, KZ (Utility model), LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW. MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

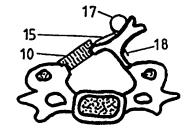
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A DEVICE TO STABILISE THE LAMINA

(57) Abstract

A device for dynamically stabilising the lamina (4) after a laminoplasty includes spacing means (10) which are shaped to engage between the severed edges of the lamina. The device also includes retaining means (17) attached to the spacing means (10) which are shaped to maintain the spacing means in an operable position. A method of dynamically stabilising the lamina after a laminoplasty is also provided, which includes the steps of positioning a spacing means (10) between the severed edges of the lamina (4), and positioning a retaining means (17) attached to the spacing means (10) to maintain the spacing means (10) in an operable position.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic	SD	Sudan
CF	Central African Republic		of Korea	SE	Sweden
CG		KR	Republic of Korea	SG	Singapore
	Congo Switzerland	KZ	Kazakhstan	SI	Slovenia
СН	•	LL LL	Liechtenstein	SK	Slovakia
CI	Côte d'Ivoire	LK .	Sri Lanka	SN	Senegal
СМ	Cameroon	LR	Liberia	SZ	Swaziland
CN	China		Lithuania	TD	Chad
CS	Czechoslovakia	LT		TG	Togo
CZ	Czech Republic	LU	Luxembourg		Tajikistan
DE	Germany	LV	Larvia	· TJ	•
DK	Denmark	MC	Monaco	π	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

A DEVICE TO STABILISE THE LAMINA

This invention relates to a device that dynamically stabilises the lamina after a laminoplasty.

BACKGROUND

Cervical spinal stenosis is a condition in which the opening for the spinal cord that runs through the vertebrae of the spinal column is not quite wide enough to comfortably accommodate the spinal cord. The result is that when the ligaments thicken or there is some bulging of the cervical discs (a natural product of wear and tear through life) the person who is affected begins to experience pressure on their spinal cord. This causes three types of symptoms:

- 15 1. It causes pain in the head, neck and arms;
 - 2. It causes weakness and/or numbness and tingling in the arms;
 - 3. It causes clumsiness in the arms and legs.

As a result of these symptoms, some people find that their mobility and their ability to undertake a normal day's work is severely affected. The obvious solution is to make more room for the spinal cord so that the pressure will not happen.

There are two methods of creating more room in the cervical spinal canal. The first is a laminectomy in which the bony structures forming the back of the canal and the associated ligaments are removed. This can lead to the swan neck deformity so that although it is a very safe operation and usually quite effective it can result in swan neck deformity which is a very difficult problem to correct and which itself causes a lot of discomfort in the neck and shoulders. This is due to the lack of the supporting structures at the back of the vertebrae which normally perform some of the work of keeping the neck in the right shape.

The alternative and increasingly popular way of doing the operation is called a laminoplasty. In this operation the back of the spine is exposed but instead of the bony structures being removed, they are altered in shape. When the bone has been weakened it is bent outwards opening the canal and providing more room for the spinal cord. The traditional problem has always been to stabilise the lamina in this new position.

One way of stabilising the lamina is to take a bone graft from the hip in the form of a rectangular plate of bone and wedge it in position to try and hold the lamina in its new, more open shape. This is generally effective but because it is not a firm arrangement can lead to some slippage and recurrent narrowing of the spinal canal. It also involves making a separate wound in the area of the hip and taking a bone graft.

It is an object of the present invention to provide a prosthesis device to dynamically stabilise the lamina after laminoplasty.

10 PRESENT INVENTION

Accordingly the invention consists in a device for dynamically stabilising the lamina after a laminoplasty comprising spacing means shaped to engage between the severed edges of the lamina and retaining means attached to said spacing means and shaped to maintain the spacing means in an operable position.

15

This invention also consists in a method of dynamically stabilising reshaped lamina after a laminoplasty comprising the steps of positioning a spacing means between the severed edges of the lamina and positioning a retaining means attached to said spacing means to maintain the spacing means in an operable position.

20

30

The invention consists in the foregoing and also envisages constructions of which the following gives examples only.

DRAWING DESCRIPTION

One preferred form of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a cross section through the back bone;

Figure 2 is a rear view of a section of the back bone;

Figure 3 is a section of the back bone with modifications made;

Figure 4 is a cross section of the back bone illustrating the modifications made in a laminoplasty;

Figure 5 shows the modified back bone with the device according to the present invention in place;

Figure 6 is a perspective view of a device according to the present invention; Figure 7 is an elevation of the device according to the present invention; and

Figure 8 shows a back view with the device fitted in place.

PREFERRED EMBODIMENT

30

Figures 1 and 2 illustrate a section through a joint in the back bone 1 with the vertebrae body 2, spinal cord 3, lamina 4 and spine 5. Figure 2 shows a rear view of a number of vertebrae.

In a laminoplasty a cut 7 is made through the lamina on one side and a weakening groove 8 is formed on the other side. This weakens the bone so that it can be deformed to a position as illustrated in figure 5, but it is necessary to stabilise the deformed lamina.

The present invention provides a stabilising device 9 illustrated in figures 6 and 7 of the accompanying drawings and shown as fitted in place in figures 5 and 8 of the accompanying drawings. It operates in a way that is effective but does not rely on rigid fixation. The device is a substantially rectangular plate 10 having shouldered longitudinal edges 11 and 12. The device can be made from stainless steel or any other suitable material which will not be rejected by the body. It is proposed to make the device from nylon, teflon and/or titanium which will be compatible with the MRI scans should such scans need to be done following surgery.

It is necessary to ensure that the plate 10 is correctly located in place in a way which will avoid or minimise any movement and for this to be achieved simply and effectively in a time efficient way. We have found that the locating device is best achieved by a spring 13 attached with two arms 14 and 15 extending from the rectangular plate formed into a spring coil 16 and 17 on each side and then continued as a U shaped section 18 joining or completing the spring clip with the U shape section 18 in use located behind the spine 5 as is particularly illustrated in figure 5 with the springs 16 and 17 fitting between the vertebrae as illustrated particularly in figure 8.

As a consequence of the present invention it has been possible to reduce the operating time by half and to lessen the theoretical likelihood of recurrent narrowing of the spine. Another significant advantage for the patient is a more comfortable resulting neck that is achieved using other known procedures. As a consequential advantage over the need for removing a bone graft from the hip, the patient will have no discomfort in the hip which is often the most painful part of the traditional laminoplasty method.

The technique applied in fitting the device uses known means to encourage fusion between the device and the cut lamina, for example, by placing bone chips obtained from the neck during the laminoplasty around the device. However, it must be appreciated that any spinal operation carries a risk and while we have been very confident that the present invention will offer an advantage and will not carry any greater risk than other posterior approach to the cervical spine, the design of the present device has been adopted to minimise or eliminate slippage of the device once its fitted and to function so that it will retain the enlarged spinal canal. It is considered that the present invention and the technique of applying the device represents a significant improvement in an area which is medically recognised as requiring particular care because of the consequences that follow from damaging the spinal cord.

CLAIMS:

5

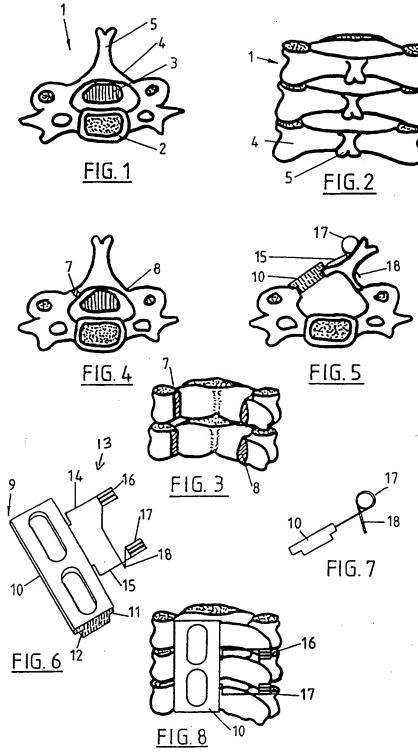
10

- A device for dynamically stabilising the lamina after a laminoplasty comprising: spacing means shaped to engage between the severed edges of the lamina; and retaining means attached to said spacing means and shaped to maintain the spacing means in an operable position.
- 2. A device as claimed in claim 1 wherein said spacing means comprises a plate of substantially rectangular configuration.
- 3. A device as claimed in claim 2 wherein said spacing means is shouldered along the longitudinal edges thereof.
- 4. A device as claimed in any one of the preceding claims wherein said retaining means comprises a spring clip having:

two arms extending from the spacing means; a U-shaped section to engage over the spine; and spring means between the arms and the U-shaped section.

- 20 5. A device as claimed in any one of the preceding claims wherein said device is made from nylon, teflon and/or titanium.
 - 6. A method of dynamically stabilising reshaped lamina after a laminoplasty comprising the steps of:
- positioning a spacing means between the severed edges of the lamina; and positioning a retaining means attached to said spacing means to maintain the spacing means in an operable position.
- 7. A method of dynamically stabilising reshaped lamina after a laminoplasty as claimed in claim 6 wherein said retaining means is positioned to engage over the spine.





INTERNATIONAL SEARCH REPORT

International Application No. PCT/NZ 96/00096

Λ.	CLASSIFICATION OF SUBJECT MATTE	SR					
Int Cl ⁶ : A6	SIB 17/70						
According to	According to International Patent Classification (IPC) or to both national classification and IPC						
В.	FIELDS SEARCHED						
	Minimum documentation searched (classification system followed by classification symbols) IPC: A61B 17/-, A61F 1/-, 2/-, 5/-						
Documentation AU: IPC as	a searched other than minimum documentation to the above	e extent that such documents are included in	the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT: Lamin: or spine: or spinal JAPIO: Lamin: or spine: or spinal							
C.	DOCUMENTS CONSIDERED TO BE RELEVA	ANT					
Category*	Citation of document, with indication, where	appropriate, of the relevant passages	Relevant to claim No.				
A	AU 76930/94 A (Societe de Fabrication de M 9 March 1995	1-7					
A	US 5304178 A (Stahurski) 19 April 1994	1-7					
A	US 5147404 A (Downey) 15 September 1992		1-7				
x	Further documents are listed in the communation of Box C	X See patent family armex					
"A" document defining the general state of the art which is not considered to be of particular relevance earlier document but published on or after the international filing date understand the principle or theory underlying the invention document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document is taken alone document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date "L" later document published after the international filing date priority date and not in conflict with the application but cite understand the principle or theory underlying the invention adcoument of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention can be considered novel or cannot be considered to involve an inventive step when the document of							
Date of the actu	al completion of the international search	Date of mailing of the international searc	h report				
16 January 199	6	10 FEB 1997					
	ing address of the ISA/AU INDUSTRIAL PROPERTY ORGANISATION 2606 Facsimile No.: (06) 285 3929	DAVID MELHUISH Telephone No. (96) 283 2426					

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/NZ 96/00096

C (Continua		D-1
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 4611582 A (Duff) 16 September 1986	:
A '		1-7
	Derwent Abstract Accession No 85-005046/01, Class P31, SU,A, 1091916 (Moscow Medical Inst) 15 May 1984	
Α	and the state of t	1-7
	·	
		·
	·	
	·	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No. PCT/NZ 96/00096

END OF ANNEX

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
AU	76930/94	CN FR WO	1114099 2709411 9506440	EP NO ZA	676933 951680 9406799	FI PL	952095 308753
us	5304178						
US	5147404	US	4874389	US	5035716		
US	4611582						
			ί				
	•						
		,					
					•		
						•	